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(54) Title: DETECTING AND QUANTIFYING HOST CELL PROTEINS IN RECOMBINANT PROTEIN PRODUCTS

(57) **Abstract:** A single-step immunoassay method, kit, and reagents for detecting and quantifying contaminant host cell proteins in a recombinant protein sample are described. The method includes the step of adding to immobilized medium comprising a capture reagent including anti-host cell protein antibodies, both the recombinant protein sample and a detection reagent comprising anti-host cell protein antibodies and a detectable moiety. The recombinant protein sample and two reagents are added simultaneously. This single-step format provides greater interaction between the capture antibody, the contaminant host cell proteins that may be present in the recombinant protein sample, and the detection antibody. By providing the opportunity for both antibodies and HCPs to interact at the same time, the one step format allows the formation of the "capture antibody-HCP-detection antibody" complex with all possible HCPs present. Thus, the HCP assay sensitivity is significantly improved, and the possibility of a false negative is significantly reduced. In addition, the one step format shortens the assay turnaround time and provides a convenient tool for measuring the HCP in the product during the course of the entire purification procedure. Quality control of the process is increased and the protein purification efficiency during process development can be measured.